

EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

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THE CITY OF HUNTINGTON,

Plaintiff,

vs.

CIVIL ACTION

NO. 3:17-01362

AMERISOURCEBERGEN DRUG
CORPORATION, et al.,
Defendants.

CABELL COUNTY COMMISSION,

Plaintiff,

vs.

CIVIL ACTION

NO. 3:17-01665

AMERISOURCEBERGEN DRUG
CORPORATION, et al.,

Defendants.

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Videotaped and Zoom video conference
deposition of JAMES RAFALSKI taken by the Defendants
under the Federal Rules of Civil Procedure in the
above-entitled action, pursuant to notice, before
Jennifer Vail-Kirkbride, a Registered Merit
Reporter, on the 11th day of September, 2020.

1 Q. Would reports written by West Virginia
2 Board of Pharmacy inspectors detailing their on-site
3 inspections of West Virginia pharmacies, including
4 West Virginia pharmacies you talked about, be useful
5 and relevant for you to review in assessing those
6 pharmacies?

7 Yes or no?

8 A. I -- it's more complicated than a yes or
9 no. It's a possibility -- [overtalking] it's a
10 possibility they could be relevant, depending on how
11 the assessment or the inspection was done.

12 Q. Okay.

13 A. Without being present and having a full
14 knowledge of what they did, I'm familiar with how,
15 you know, my DEA experience was more of a
16 recordkeeping inspection in the State of Michigan,
17 making sure that the records are maintained for, you
18 know, specifically prescriptions and drug storage
19 and records are on-site.

20 There wasn't -- unless it was a
21 focused investigation in Michigan - I'm only talking
22 about my experience with Michigan and somewhat with
23 Ohio - they weren't typical diversion investigations
24 unless that was their purpose outside of an

1 but everything -- every little shred and fact of --
2 is important. I don't want to diminish, but it
3 wouldn't have a high level of relevancy to me.

4 Q. Would it be relevant to you if one of the
5 pharmacies you talked about was inspected by the
6 West Virginia Board of Pharmacy and they found that
7 there was "no improper dispensing" at that pharmacy?
8 Would that be relevant to you, yes or no?

9 A. The same as my earlier reply, I --
10 everything is important, but without being present
11 or knowing exactly, you know, how the investigation
12 is conducted and what they looked at, uhm, I can't
13 make a judgment on that.

14 Q. Well, would you want to know if one of the
15 pharmacies you talked about, the West Virginia Board
16 of Pharmacy, went there and said, "There is no
17 improper dispensing here," or, "There are no illegal
18 sales here" or "The prescriptions are for a
19 legitimate medical purpose here," would you want to
20 know that, yes or no?

21 MR. FULLER: Form. You can answer any
22 way that you feel appropriate, Ralph.

23 MR. SCHMIDT: I am going to note for
24 the record that counsel just instructed the witness

1 to be evasive, and if it continues we'll raise that.

2 MR. FULLER: We can call Wilkes now if
3 you want.

4 Q. Can you answer that, Mr. Rafalski?

5 A. It's not just a simple yes or no. I really
6 don't know the realm of the type of inspections so
7 for me to say it's essential or not, like I said
8 before, everything is important but it's how -- the
9 level of importance. And I just -- you know, as I
10 answered earlier, I don't know exactly how the
11 inspector, confidence in their capabilities, so it
12 wouldn't be highly relevant, but it's -- it's just
13 another fact.

14 Q. Okay. And that's why I am going to ask you
15 to focus on my question. I didn't ask you if it was
16 essential; I didn't ask you if it was relevant. I
17 asked that a moment ago. My question to you is
18 simply: Would you want to know if a West Virginia
19 Board of Pharmacy inspector went to one of the
20 pharmacies you talked about and found that there
21 was, quote, "no improper prescribing" or, quote, "no
22 illegal sales" or that prescriptions were issued,
23 quote, for "legitimate medical purpose," is that
24 something you would want to know in doing your work,

1 these orders were actually evaluated and the
2 suspicion was eliminated on the first order;
3 correct?

4 A. Well, I draw my assumption on the due
5 diligence that none of them based on the conduct of
6 the companies in regards to how they evaluated their
7 own suspicious orders and I didn't see -- I saw very
8 limited to know due diligence on their own
9 suspicious orders, so I wouldn't have a high
10 expectation that there would have been due diligence
11 on any of these that were identified by the flag.

12 Q. Okay. And I want to get away from
13 assumptions and expectations because I don't think
14 that's proper for expert witnesses. I want to focus
15 on what you know and what you've done. Am I correct
16 that in method -- well, do you know -- sticking with
17 Method A, do you know how many of those orders are
18 the first flagged orders and how many are the ones
19 that you just bring along for the ride because of
20 the assumption that there was no diligence to
21 justify later orders for that customer; do you know?

22 A. The first one is the flagged order.

23 Q. Do you know how many of the first ones
24 there are, as opposed to the later ones, that are

1 brought along based on your assumption?

2 A. For each defendant there is one first order
3 and every subsequent one is flagged if we are
4 talking about Masters A?

5 Q. Yes, how many first orders?

6 MR. FULLER: Object to form.

7 Q. Like, let's take an example of the 11.6
8 million oxycodone orders for ABDC, how many of those
9 11.6 million were initial orders and how many of
10 them just came along due to the assumption?

11 A. One initial order.

12 Q. And then the remaining 11,610,919 orders
13 were cumulatively flagged?

14 A. Yes, sir.

15 Q. Okay. And is that true for every one of
16 your defendants, that there was only one initial
17 order flagged and then every other order you
18 identify was flagged based on the assumption that
19 because there was not diligence on that initial
20 order, the subsequent orders should have been held?

21 A. So -- just so I'm clear, the totality of
22 all of -- all of the figures here or are we talking
23 about Masters A?

24 Q. Masters A. Just Masters A.

1 A. All right. I didn't want to answer
2 incorrectly or make assumptions. The first one on
3 Masters A, each defendant would be yes to that
4 answer, the first one.

5 Q. Okay. And so am I correct that for Method
6 A, for each defendant there is one, single order
7 that drives the remaining millions of orders that
8 you have flagged?

9 A. Yes, sir.

10 Q. And have you looked -- have you identified
11 those single orders for -- in their entirety for
12 McKesson, Cardinal, and ABDC?

13 A. I don't understand the question, sir.

14 Q. Have you looked at those initial orders for
15 McKesson, Cardinal, and ABDC that are the initial
16 flagged orders of your Method A?

17 A. No, sir.

18 Q. Do you know the diligence that was
19 conducted on those initial flagged orders for
20 McKesson, Cardinal, and ABDC, not having looked at
21 the actual orders themselves?

22 A. Well, I couldn't know the diligence if I
23 answered I didn't know the orders. And as I
24 answered earlier, understanding your question, I

1 identified, the millions of orders you identify were
2 actually blocked that if your hypothetical Method A
3 were actually applied ever in the real world,
4 including in Cabell County, can you rule out that
5 some patients would be denied medically necessary
6 prescription opioids? Are you able to rule that
7 out?

8 A. Well, I think you are asking me --

9 Q. That's a yes or no question.

10 A. I don't think it is, Mr. Schmidt, because
11 you're asking me to give a hypothetical answer to a
12 hypothetical question, and --

13 Q. No, I am not. [Overtalking] Let me ask it
14 again then instead of arguing over the
15 question. Had your Method A been applied and these
16 millions of orders been blocked, do you know one way
17 or another whether that would have resulted in
18 patients in Cabell County being deprived of
19 medically necessary prescription opioids? Do you
20 know?

21 MR. FULLER: Object to form. Ralph,
22 you can answer the best you can.

23 A. I didn't do an evaluation on that. I do
24 not know.

1 A. Yes, maintain -- maintain "of effective
2 controls against diversion of particular controlled
3 substances;" yes, sir.

4 Q. And then they also failed to construct and
5 operate an appropriate suspicious order monitoring
6 system; is that right?

7 A. Yes, sir.

8 Q. And that they each shipped orders that
9 would be determined to be suspicious; is that
10 correct?

11 A. Yes, sir.

12 Q. Now, let's talk about what your opinion is
13 and has been related to obligations under the
14 CSA. If an order is determined to be suspicious,
15 it's your opinion that it should be halted; correct?

16 A. Yes, sir.

17 Q. And that it also should be reported to the
18 DEA; is that right?

19 A. Yes, sir.

20 Q. Now, each registrant has the ability to
21 conduct due diligence on any particular order; is
22 that fair?

23 A. That's a correct statement. I agree with
24 that.

1 Q. And then the due diligence can clear up any
2 suspicion; is that true?

3 A. Yes, sir, that's a --

4 MR. SCHMIDT: Can I just have a
5 running objection? This is Paul Schmidt. Could I
6 just have a running objection to all of the leading
7 of your witness so I don't have to keep --

8 MR. FULLER: Absolutely, sure. Sure,
9 no problem.

10 MR. SCHMIDT: Thank you.

11 Q. Additionally, the -- I think it was mainly
12 Mr. Schmidt questioned you about this position that
13 you had Mr. McCann run where once an order is
14 triggered, all future orders are triggered because
15 of the lack of due diligence. I think you
16 referenced it in your report, but can you tell me
17 has the DEA taken a position, to your knowledge, on
18 that same compliance requirement?

19 A. I think they have. I recall the testimony
20 of Mr. Prevoznik in his deposition where he takes
21 that position that once an order is identified as
22 suspicious, that it should be held and shipping
23 should be terminated until the diversion is
24 dispelled, or ruled out.

1 diligence file; is that correct?

2 A. Yes, sir. Well, a little more than
3 documented. I guess when you say, "documented," I
4 would expect to be documented, but -- and especially
5 based on the Masters ruling, it's a little more than
6 just documented to say that it occurs. There's some
7 expectation that there'd be a confirmation of those
8 things actually occurring versus just taking the
9 registrant's word for it.

10 Q. The methodologies, the way you've had them
11 utilized, they identify triggering events and,
12 again, I want to make it clear for the record, you
13 didn't dig down and look at every triggering event
14 in the hundreds of thousands of lines of data that
15 were provided by the defendants and via the ARCOS
16 data; correct?

17 A. That's correct, sir.

18 Q. So you can't identify or you didn't go
19 through the line-by-line transactions to identify
20 the suspicious orders, but your methodology was to
21 set out triggers and then with the assumption,
22 identify suspicious orders that should have been
23 reported; correct?

24 A. Uhm, yes, sir.

1 A. I would.

2 Q. You re -- reviewed defendants' experts
3 reports; is that right?

4 A. Yes, I did.

5 Q. Do you see anywhere where they pointed to
6 specific sufficient due diligence for any of the
7 customers in Cabell or Huntington?

8 A. I have not.

9 Q. There's one thing I want to clear up, too,
10 earlier. When you and Mr. Schmidt were going back
11 and forth about the methodologies and how they
12 worked, I think you indicated for each defendant
13 there may be one triggering order. It would
14 actually be one triggering order for each of their
15 customers; is that right?

16 A. Yes, sir.

17 MR. SCHMIDT: Objection.
18 Leading. And I'm just going to note for the record
19 that directly changing the witness's testimony
20 through a leading question is improper.

21 Q. I think there was also some questions about
22 the code that Mr. McCann did. When you use the term
23 "code" what does that mean, Mr. Rafalski?

24 A. It's a -- it's an algorithm. It's a series